

U.S. APPLICATION No. 10/607,070
ATTORNEY DOCKET No. 64118.000140

III. REMARKS

Claims 1-33 are currently pending. The Office Action has been received and carefully considered. Reconsideration of the assertions made in the Office Action is respectfully requested based on the following remarks.

A. ELECTION/RESTRICTION REQUIREMENT

Applicants note with appreciation the withdrawal of the restriction requirement. Therefore, claims 1-33 are currently being examined on the merits.

B. ALLOWABLE SUBJECT MATTER

Applicants also note with appreciation the indication that claims 12, 16, and 30 would be allowable if rewritten in independent form. As set forth below, however, Applicants submit that the claims on which these claims depend are allowable.

C. REJECTIONS UNDER 35 U.S.C § 103(a)

1. Claims 1-11, 13-15, 17-25 and 31-33

Claims 1-11, 13-15, 17-25 and 31-33 stand rejected as allegedly rendered obvious by U.S. Patent No. 6,740,900 to Cragg *et al.* ("Cragg") in view of U.S. Patent No. 6,613,044 to Carl. Specifically, the Office Action asserts that "Cragg *et al.* disclose the claimed invention except for the obtaining transpedicular access to the first intervertebral disk." Office Action, Page 5. Thus, the Office Action refers to Carl, which allegedly discloses "obtaining transpedicular access to the first intervertebral disk as one of the variety of surgical approaches practiced by surgeons to provide access to intervertebral discs and is less invasive to abdominal organs than an anterior surgical approach (col. 5, lines 4-25)." Office Action, Page 5. Thus, the Office Action contends that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Cragg *et al.* to obtain transpedicular access to the first intervertebral disk in view

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of Carl because it is one of the variety of surgical approaches practiced by surgeons to provide access to intervertebral discs and it is less invasive to abdominal organs than an anterior surgical approach.” *Id.* Applicants respectfully disagree, as the Office Action has failed to establish a prima facie case of obviousness.

In order to establish a prima facie case of obviousness, at least three criteria must be met. First, there must be some motivation or suggestion to make the proposed combination or modification of the references. Notably, “the teaching or suggestion to make the claimed combination must be found in the prior art, and not based on the applicant’s disclosure.” MPEP 2142 (discussing In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991)). Second, there must be a reasonable expectation of success. Finally, the combined or modified references must teach or suggest all claim limitations. See MPEP 2142 et seq.

There is no evidence of motivation to combine the disclosure of Cragg with that of Carl. First, Cragg is directed to methods and apparatuses “for forming one or more axial bore through spinal vertebral bodies for performing surgical procedures for receiving spinal implants, or for other medical reasons....” Cragg, Col. 5, l. 67- col. 6, l. 3. Cragg does not disclose or suggest performing surgery by transpedicular access.” Carl discloses “devices and methods for treating the tissue in and around the intervertebral disc through localized hypothermia therapy to reduce pain or to restore function in the disc and surrounding tissue.” Carl, Col. 2, ll. 31-33 (emphasis added). Although both disclosures relate generally to the spine, Cragg is directed to forming bores in spinal vertebral bodies (Cragg, Col. 5, l. 67 - col. 6, l. 3), while Carl does not form a bore in a spinal vertebral body, but instead treats intervertebral discs with a cryoprobe (Carl, Col. 5, l. 32-39).

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Therefore, one of ordinary skill in the art, upon seeing Carl's disclosure, would not be motivated to modify Cragg to form a channel through a pedicle in a vertebra.

Further, the one alleged source of motivation in Carl - the conjecture that "[t]ranspedicular and presacral or transsacral ... approaches are also possible" does not provide motivation for the combination. Carl, Col. 5, ll. 16-19. The fact that it may be possible to use a hypothermia device, such as a cryoprobe, to treat intervertebral disc tissue via a transpedicular approach does not suggest that all surgeries involving the spine would be amenable to such an approach.

The current rejection appears to be the result not viewing the invention as a whole. Instead, the Office Action has broken the invention into its component parts, and has alleged that there is a prior art reference that corresponds to each claim element. The Federal Circuit recently again held that this practice is improper:

in making the assessment of differences between the prior art and the claimed subject matter, section 103 specifically requires consideration of the claimed invention "as a whole." ... The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. [*Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004)]. Without this important requirement, an obviousness assessment might successfully break an invention into its component parts, then find a prior art reference corresponding to each component. Id. This line of reasoning would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. Further, this improper method would discount the value of combining various existing features or principles in a new way to achieve a new result-often the essence of invention. Id.

Princeton Biochemicals, Inc. v. Beckman Coulter, Inc., 411 F.3d 1332, 1337 (Fed. Cir. 2005) (emphasis added). Therefore, the Office Actions rejection, which has broken the invention into its component parts, and has alleged that the component parts are disclosed by either Cragg or Carl, is improper.

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In addition, the combined references fail to disclose or suggest all claim limitations. Specifically, independent claim 1 recites:

1. (Original) A method for treating diseases and conditions that change the spacial relationship between a first vertebral body of a first vertebra, a second vertebral body of a second vertebra adjacent the first vertebra, and a first intervertebral disk between the first vertebral body and the second vertebral body, or that cause instability of the vertebral column, or both, and a method that allows the surgeon to access the first intervertebral disk to restore a more normal three-dimensional configuration of the first intervertebral disk between the first vertebral body and the second vertebral body, the method comprising:

- a) selecting a patient;
- b) obtaining transpedicular access to the first intervertebral disk by creating a channel through a pedicle of the first vertebra; and
- c) removing at least part of the first intervertebral disk through the transpedicular access.

Appl'n, Claim 1 (emphasis added). Contrary to the Office Action's assertion, Carl does not disclose "obtaining transpedicular access to the first intervertebral disk by creating a channel through a pedicle of the first vertebra." Instead, as noted above, the only mention of "transpedicular access" is in mere conjecture in Cragg -- "Transpedicular and presacral or transsacral ... approaches are also possible." Carl, Col. 5, ll. 16-19. Carl makes no further mention of transpedicular access; in fact, the disclosure focuses on the use of a cryoprobe to treat a thermally-transmissive hypothermia region of a disc annulus and tissue. Therefore, because the combination of Cragg and Carl would fail to disclose or suggest all claim limitations, Applicants respectfully request that the rejection of independent claim 1, and all claims dependent thereon, be withdrawn.

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2. Claims 25 and 26

Claims 25 and 26 stand rejected as allegedly rendered obvious by Cragg in view of Carl, and further in view of U.S. Patent No. 6,712,853 to Kuslich. Specifically, the Office Action asserts that Cragg and Carl disclose the invention except for “inserting a fusion agent containment device and partially filling it with fusion agent, the fusion agent containment device comprising a band of thin, biocompatible, deformable material having shape memory and configured to expand into a circular shape when undeformed.” Office Action, Pages 5-6. To cure this deficiency, the Office Action refers to Kuslich, which allegedly discloses “a fusion agent containment device inserted into the vertebral disc (col. 9, lines 7-8) and partially filling it with fusion agent (col. 10, lines 25-30), the fusion agent containment device comprising a band of thin, biocompatible, deformable material having shape memory and configured to expand into a circular shape when undeformed in order to stabilize a disc.” *Id.* at 6. Thus, the Office Action contends that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Cragg et al. in view of Carl including inserting a fusion agent containment device into the vertebral disc and partially filling it with fusion agent, the fusion agent containment device comprising a band of thin, biocompatible, deformable material having shape memory and configured to expand into a circular shape when undeformed in view of Kuslich in order to stabilize a disc.” *Id.* Applicants respectfully disagree, as the Office Action has again failed to establish a prima facie case of obviousness.

As discussed above, there is no evidence of motivation to combine Cragg and Carl, and the combination of Cragg and Carl does not disclose “obtaining transpedicular access to the first intervertebral disk by creating a channel through a pedicle of the first vertebra.” Kuslich, which discloses “an expandable tubular

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member or band which has side wall and may include a fill opening" that is used to "support the diseased and/or weakened annulus of the disc," Kuslich, Col. 4, ll. 42-56. Thus, Kuslich does not cure the shortcomings of the proposed combination of Cragg and Carl. Therefore, Applicants respectfully request that the rejection of these claims be withdrawn.

3. Claims 28 and 29

Claims 28 and 29 stand rejected as allegedly rendered obvious by Cragg in view of Carl, and further in view of U.S. Patent No. 6,102,950 to Vaccaro. Specifically, the Office Action assert that the combination of Cragg and Carl does not disclose "the distraction system comprising a proximal connecting portion, a distal distracting portion comprising a plurality of strips, where each strip is deformable from an extended configuration to a curled configuration, each strip having a distal and proximal end, where the proximal ends are joined to the proximal connecting portion." Office Action, Page 7. To cure these deficiencies, the Office Action refers to Vaccaro, which allegedly discloses

an introducer comprising a proximal insertion portion (ref. #32) and a distal anchoring portion (rest of ref. #20 located distal to ref. #32), a plurality of deformable, spacing components (ref. #80 and 40), each spacing component having a central opening (ref. #36 and 88) and a plurality of extensions (ref. #82 and 44), and each spacing component is configured to stack onto the insertion portion of the introducer, as well as the distraction system comprising a proximal connecting portion(ref. #60), a distal distracting portion comprising a plurality of strips (ref. #50), where each strip is deformable from an extended configuration to a curled configuration, each strip having a distal and proximal end, where the proximal ends are joined to the proximal connecting portion, in order to provide an intervertebral body fusion device that provides the proper angle of lordosis between the vertebrae (col. 4, lines 40-45).

Id. Thus, the Office Action contends that

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[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Cragg et al. in view of Carl and using a distraction system comprising an introducer comprising a proximal insertion portion and a distal anchoring portion, a plurality of deformable, spacing components, each spacing component having a central opening and a plurality of extensions, and each spacing component is configured to stack onto the insertion portion of the introducer, a proximal connecting portion, a distal distracting portion comprising a plurality of strips, where each strip is deformable from an extended configuration to a curled configuration, each strip having a distal and proximal end, where the proximal ends are joined to the proximal connecting portion in view of Vaccaro in order to provide an intervertebral body fusion device that provides the proper angle of lordosis between the vertebrae.

Id. at 708. Applicants respectfully disagree, as the Office Action has again failed to establish a prima facie case of obviousness.

As discussed above, there is no evidence of motivation to combine Cragg and Carl, and the combination of Cragg and Carl does not disclose “obtaining transpedicular access to the first intervertebral disk by creating a channel through a pedicle of the first vertebra.” Vaccaro, which discloses “[a]n intervertebral body fusion device ... [that] is surgically placed intervertebrally into the spine from an anterior surgical approach.” Vaccaro, Col. 4, ll. 16-22. Thus, Vaccaro does not cure the shortcomings of the proposed combination of Cragg and Carl. Therefore, Applicants respectfully request that the rejection of these claims be withdrawn.

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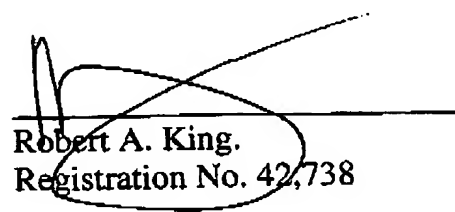
IV. CONCLUSION

No additional fee is believed to be required. Nevertheless, in the event that the U.S. Patent and Trademark Office requires any additional fee, please charge such fee to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,
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